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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,059	03/12/2004	Kenneth A. Alley	ALLE-P12-US	6741
21616	7590	11/01/2004	EXAMINER	
LAW OFFICES OF MARK A. GARZIA, P.C. 2058 CHICHESTER AVE BOOTHWYN, PA 19061			PATEL, MITAL B	
			ART UNIT	PAPER NUMBER

3743

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/799,059

Applicant(s)

ALLEY, KENNETH

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Reference characters 58 and 59. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pressurized chamber and pressurized cartridges must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

3. There is a lack of antecedent basis for the following limitations:

- Claim 8, lines 10-11, "the mouthpiece"

Correction is required.

4. With respect to claim 7, the use of the term and/or renders the claim vague and indefinite. Correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 3, 5, 6, 7, 8, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerk et al (US 5,301,666).

7. **As to claim 1**, Lerk et al teaches an inhaler for delivering drugs/medications by inhalation, the inhaler device comprising of: a) a housing (**See Fig. 2**) defining an inlet, an outlet **at 29** spaced from said inlet, and an airflow path (**See Fig. 2 with respect to arrows**) from said inlet to said outlet; b) a plurality of storage chambers **12** for storing a plurality of medications; c) means **14, 101, 43, 16** that communicate with said drug storage chambers for withdrawing a pre-determined amount of medication from one or more chambers; and d) means **21,22** to simultaneously dispense said withdrawn medication during a single inhalation activity/event.

8. **As to claim 2**, Lerk et al teaches an inhaler wherein said outlet comprises a mouthpiece **10,11,29**.

9. **As to claim 3**, Lerk et al teaches an inhaler wherein said mouthpiece isolates each individual drug passageway during each inhalation activity/event (**See Col. 5, lines 15-33**).

10. **As to claim 5**, Lerk et al teaches an inhaler wherein said inhaler comprises a plurality of dosing discs **1** (**See Col. 4, lines 37-53**).

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11. **As to claim 6**, Lerk et al teaches an inhaler where said inhaler further comprises a plurality of channels **6, 43** for isolate said medications until they exit the outlet during the evacuation process.

12. **As to claim 7**, Lerk et al teaches an inhaler where said inhaler includes a combination of a dry powder drug with a pressurized chamber (**See Col. 11, lines 30-68, and Col. 12, lines 1-34**) to help evacuate the drug and/or to include an additional aerosol medication simultaneously with the dry powder.

13. **As to claim 8**, Lerk et al teaches an inhaler for delivering drugs/medications by inhalation, the inhaler device comprising of: a) a housing (**See Fig. 2**) defining an inlet, an outlet **at 29** spaced from said inlet, and an airflow path from said inlet to said outlet (**See Fig. 2 with respect to arrows**); b) a plurality of storage chambers **1** for storing a plurality of medications; c) a rotatable dosing disc having a plurality of dosing wells **12** that communicate with said drug storage chambers for withdrawing a pre-determined amount of medication from one or more chambers; and d) air passageway platform having a plurality of passageway channels **14, 36, 37**, said air passageway channels communicating with both the dosing wells and said outlet of the mouthpiece **10, 11, 29** to define multiple air passageways for delivering said withdrawn medication during a single inhalation activity/event.

14. **As to claim 9**, Lerk et al teaches an inhaler wherein said multiple air passageways allow biaxial air flow to move the medicaments through the inhaler and out the outlet (**See Fig. 2 with respect to the arrows**).

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15. **As to claim 10**, Lerk et al teaches an inhaler further comprising pressurized cartridges that communicate with the dosing wells for ensuring the complete evacuation of the medicaments from the wells, the air passageways and the outlet during the inhalation event (**See Col. 11, lines 30- 68, and Col. 12, lines 1-34**).

### ***Allowable Subject Matter***

16. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor render obvious the overall claimed combination of an inhaler wherein the mouthpiece includes a plurality of drug passageways for isolating each individual medication as the user of the device evacuates the prescribed dose.

### ***Conclusion***


18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6718972, US 6681768, US 6575160, US 6367473, US 6240918, US 6116239, US 5616670, US 5394868, and US 5243970.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 10/31/04  
Mital B. Patel  
Examiner  
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